

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Safeguard Individual Liberty - The bill establishes an additional situation where a patient's blood can be tested for HIV without their consent.

B. EFFECT OF PROPOSED CHANGES:

Present Situation

According to the Department of Health, there were 5,223 HIV cases and 4,960 AIDS cases reported in Florida in 2006.¹

The United States Occupational Safety and Health Administration (OSHA) estimates that 5.6 million workers in the health care industry are at risk of occupational exposure to bloodborne pathogens.² Exposure that might place health care personnel at risk for HIV infection could occur through an injury by needlestick, instruments, or sharps; or contact of mucous membranes or nonintact skin (e.g., exposed skin that is chapped, abraded, or afflicted with dermatitis) with blood or body fluids.³ Risks vary with the type and severity of exposure. The average risk for HIV transmission after exposure to HIV-infected blood via a sharp object has been estimated to be approximately 0.3% and after a mucous membrane exposure, approximately 0.09%. Although episodes of HIV transmission after nonintact skin exposure have been documented, the average risk for transmission by this route has not been precisely quantified, but is estimated to be less than the risk for mucous membrane exposures.⁴

Post-Exposure Prophylaxis

In 2004, the federal Food and Drug Administration approved a rapid HIV test that provides screening results with over 99 percent accuracy in as little as 20 minutes. Once exposure to HIV is confirmed, a person may begin post-exposure prophylaxis treatment (PEP). According to Merriam-Webster's dictionary, prophylaxis means "measures designed to preserve health and prevent the spread of disease." PEP means taking antiretroviral medications as soon as possible after exposure to HIV, so that the exposure will not result in HIV infection. Antiretroviral agents from five classes of drugs are currently available to treat HIV infection. The Centers for Disease Control and Prevention (CDC) recommend two- or-more drug PEP regimens on the basis of the level of risk for HIV transmission represented by the exposure.⁵

In September 2005, the CDC stated, "Rapid HIV testing of source patients can facilitate making timely decisions regarding use of HIV PEP after occupational exposures to sources of unknown HIV status."⁶ The CDC also advises that PEP "should be initiated as soon as possible, preferably within hours rather than days of exposure."⁷

¹ Department of Health, Bureau of HIV/AIDS, "HIV/AIDS: United States vs. Florida Sheet", http://www.doh.state.fl.us/Disease_ctrl/aids/updates/facts/2006_US_VS_FL_Fact_Sheet.pdf (last visited March 11, 2008).

² U.S. Occupational Safety and Health Administration, <http://www.osha.gov/SLTC/bloodborne pathogens/recognition.html> (last visited March 11, 2008).

³ Section 381.004(2)(c), F.S.

⁴ Panlilio, Adelisa, "Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis," National Center for Infectious Diseases, September 30, 2005, <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5409a1.htm> (last viewed March 12, 2008).

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

A person receiving PEP should complete a full four-week regimen, unless the source patient is later determined to be HIV-negative, in which case the PEP should be discontinued. However, as a result of the frequency, severity, and duration of side effects, many people do not complete a full four-week course of therapy. A typical dosage for four weeks can cost \$600 to \$1,000 including the medicine, blood tests, and clinic visits.⁸

Informed Consent

Section 381.004(3), F.S., specifies that an HIV test may not be ordered without first obtaining the informed consent of the person upon whom the test is being performed. However, s. 381.004(3)(h), F.S., details the exceptions to this requirement when a blood sample may be tested for HIV without the informed consent of the person upon whom the test is being performed.

According to s. 381.004(3)(h)10.-12., F.S., medical and nonmedical personnel exposed to HIV during the course of their employment or emergency treatment can have an individual's blood tested for HIV without consent when:

- The source will not willingly consent or cannot be located, but the physician determines there has been a significant exposure to HIV; or
- The source dies.

To test an individual's blood for HIV without his or her consent, the blood sample must have been previously obtained for other purposes or obtained during the medical emergency. The individual must be informed of the HIV test and offered counseling.

If there is no previously obtained blood sample available and the source patient refuses to voluntarily submit to an HIV test, the medical personnel or the employer acting on behalf of the medical personnel may seek a court order directing the source of the exposure to submit to HIV testing.⁹

The term "medical personnel" includes a licensed or certified health care professional, an employee of a health care professional or health care facility, employees of a laboratory, personnel of a blood bank or plasma center, a medical student or other student who is receiving training as a health care professional at a health care facility, and a paramedic or emergency medical technician certified to perform life support procedures.¹⁰

The following information must be documented only in the medical personnel's file by a licensed physician when an individual's blood is tested for HIV without their consent:

- All information concerning the performance of an HIV test;
- Any HIV test results; and
- Documentation by the licensed physician that, in his or her medical judgment, the HIV test was medically necessary due to a significant exposure to HIV.

This information may only be entered into the tested individual's medical file if the person provides written consent.

Section 384.287, F.S., specifies that a law enforcement or correctional officer; support personnel employed by the Department of Law Enforcement; firefighter; or ambulance driver, paramedic, or emergency technician who comes into contact with a person in such a way that a significant exposure has occurred may request that the source person be screened for a sexually transmissible disease that can be transmitted through a significant exposure. If the source person will not voluntarily submit to screening, the employee may seek a court order directing the source person to submit to screening. The employee must also be screened for the same sexually transmissible disease.

⁸ University of San Francisco AIDS Research Institute, "What is Post-Exposure Prevention?," <http://www.caps.ucsf.edu/pubs/FS/pdf/PEPFS.pdf> (last visited March 13, 2008).

⁹ Section 381.004(3)(h)10.f. and 11.f., F.S.

¹⁰ Section 381.004(3)(h)10., F.S.

Effect of Proposed Changes

The bill allows an HIV test to be ordered on the available blood of a source patient in the event of a significant exposure if consent cannot be obtained from the patient within the time period necessary to perform the test and begin prophylactic treatment of the exposed medical personnel. This includes instances when the source patient is unconscious, unavailable, or otherwise unable to consent to testing.

The bill also directs appropriate medical personnel under the supervision of a licensed physician to document that a significant exposure has occurred and the results of an HIV test are medically necessary to determine the course of treatment for the medical personnel. The medical personnel would base these decisions on a written protocol. This is currently done by a licensed physician in his or her medical judgment.

C. SECTION DIRECTORY:

Section 1: Amends s. 381.004, F.S., providing conditions under which an HIV test on a blood sample of an individual who has not given consent may be performed and requiring documentation by certain medical personnel

Section 2: Provides an effective date of July 1, 2008.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenues.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The department has sufficient rulemaking authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The Department of Health suggested the following amendments:

- Written protocols should follow the Centers for Disease Control (CDC) and Prevention's HIV post-exposure prophylaxis guidelines published in the Morbidity and Mortality Weekly Report dated September 30, 2005.

On line 108, 167, and 211 delete those lines and insert:

protocols based on the National Centers for Disease Control and Prevention's guidelines on HIV post-exposure prophylaxis and in the physician's medical judgment, the

- Clarify the application to (11).

On line 157, delete that line and insert:

exposed medical or nonmedical personnel. ~~The individual's refusal to consent,~~

D. STATEMENT OF THE SPONSOR

No statement submitted.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES